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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

EVOKE PHARMA, INC., Plaintiff, v. TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No.: _____ COMPLAINT FOR PATENT INFRINGEMENT *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Evoke Pharma, Inc. ("Evoke" or "Plaintiff"), by and through its attorneys, brings this Complaint against Teva Pharmaceuticals, Inc. ("Teva Inc.") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Teva" or "Defendant"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 8,334,281 ("the '281 patent") and 11,020,361 ("the '361 patent") (collectively, the "GIMOTI® Patents") under the patent laws of the United States of America, Title 35, United States Code, arising out of the submission by Teva of Abbreviated New Drug Application ("ANDA") No. 216931 to the United States Food and Drug Administration ("FDA") seeking approval of a generic version of

Evoke's metoclopramide nasal spray that is the subject of New Drug Application ("NDA") No. 209388, hereinafter referred to as Evoke's "GIMOTI® Product" or "GIMOTI®." Evoke seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and other applicable laws for Teva's infringement of the GIMOTI® Patents.

THE PARTIES

2. Evoke is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 420 Stevens Avenue, Suite 370, Solana Beach, CA 92075.

3. On information and belief, Teva Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

4. On information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq*., and from Teva's submission of ANDA No. No. 216931 ("Teva's ANDA").

6. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e)(2).

7. On information and belief, this Court has personal jurisdiction over Teva because of, among other things, Teva's persistent and continuous contacts with New Jersey. Teva is "at home" in New Jersey with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Teva has purposefully availed itself of the benefits and protections of New Jersey's laws

such that it should reasonably anticipate being haled into court here. On information and belief, Teva regularly and continuously transacts business in New Jersey, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in New Jersey. On information and belief, Teva derives substantial revenue from the sale of those products in New Jersey, and has availed itself of the privilege of conducting business within New Jersey.

8. Teva USA is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5000583. Teva's principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054 is listed as an additional address on the registration certificate.

9. Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business in the State of New Jersey under Entity Identification No. 0100250184.

10. Teva Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business in the State of New Jersey under Entity Identification No. 0450614134.

11. Teva Inc. sent Evoke a letter dated February 24, 2022 ("Teva's Notice Letter"), stating that Teva Inc. filed Teva's ANDA seeking approval from FDA to engage in the commercial manufacture, use, or sale within the United States, including, upon information and belief, in the State of New Jersey, of a generic version of Evoke's GIMOTI® (metoclopramide) nasal spray Eq. 15 mg Base/Spray ("Teva's ANDA Product") prior to the expiration of the GIMOTI® Patents.

12. Upon information and belief, Teva Inc. and Teva USA are acting in concert with each other with respect to commercially manufacturing, marketing, distributing, and/or selling

pharmaceutical products throughout the United States, and will do the same with respect to Teva's ANDA Product that is the subject of ANDA No. 216931 for which Teva has sought FDA approval.

13. Teva has regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Alkermes, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 2:20-cv-12470 (D.N.J.); *Tris Pharma, Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 2:20-cv-05212 (D.N.J.); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 3:18-cv-11215 (D.N.J.).

14. Upon information and belief, this judicial district is a likely destination of the product that is the subject of Teva's ANDA.

15. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

16. Upon information and belief, Teva Inc. has a regular and established place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

17. Upon information and belief, Teva USA has a regular and established place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

18. Upon information and belief, Teva Inc. has committed acts of infringement in this judicial district by, among other things, submitting ANDA No. 216931 from within this judicial district and/or engaging in activities related to the submission of ANDA No. 216931 within this judicial district, and/or directing some or all of the ANDA submission-related from within the judicial district.

19. Upon information and belief, Teva USA has committed acts of infringement in this judicial district by, among other things, submitting ANDA No. 216931 from within this judicial

district, and/or engaging in activities related to the submission of ANDA No. 216931 within this judicial district, and/or directing some or all of the ANDA submission-related activities from within the judicial district.

20. Upon information and belief, Teva Inc. and Teva USA are acting in concert with each other with respect to the submission of ANDA No. 216931 and/or activities related to the submission of ANDA No. 216931.

EVOKE'S GIMOTI® PRODUCT

21. Evoke holds approved NDA No. 209388 for a metoclopramide nasal spray product, which is prescribed and sold under the trade name GIMOTI®.

22. Evoke's GIMOTI® Product is an FDA approved dopamine-2 (D_2) antagonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

PATENTS-IN-SUIT

23. The '281 patent, entitled "Nasal Formulations of Metoclopramide," was duly and legally issued on December 18, 2012, from United States Patent Application No. 12/645,108. A true and correct copy of the '281 patent is attached to this Complaint as Exhibit A.

24. The face of the '281 patent names Evoke as assignee. Evoke, as assignee, owns all rights, title, and interest in the '281 patent.

25. Pursuant to 21 U.S.C. § 355, the '281 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 209388 and Evoke's GIMOTI® Product.

26. Evoke's GIMOTI® Product is covered by one or more claims of the '281 patent.

27. The '361 patent, entitled "Nasal Formulations of Metoclopramide," was duly and legally issued on June 1, 2021, from United States Patent Application No. 16/181,841. A true and correct copy of the '361 patent is attached to this Complaint as Exhibit B.

28. The face of the ’361 patent names Evoke as assignee. Evoke, as assignee, owns all rights, title, and interest in the ’361 patent.

29. Pursuant to 21 U.S.C. § 355, the ’361 patent is listed in the Orange Book in connection with NDA No. 209388 and Evoke’s GIMOTI® Product.

30. Evoke’s GIMOTI® Product is covered by one or more claims of the ’361 patent.

INFRINGEMENT BY TEVA

31. Teva’s Notice Letter, dated February 24, 2022, notified Evoke that it had submitted ANDA No. 216931 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Evoke’s GIMOTI® Product before the expiration of the ’281 and ’361 patents.

32. The ’281 patent expires May 16, 2030, and the ’361 patent expires December 22, 2029.

33. On information and belief, Teva is seeking FDA approval to engage in the commercial manufacture, use, and sale of Teva’s ANDA Product before the expiration of the ’281 and ’361 patents.

34. On information and belief, Teva intends to engage in commercial manufacture, use, and sale of Teva’s ANDA Product promptly upon receiving FDA approval of ANDA No. 216931.

35. By submitting ANDA No. 216931, Teva has represented to FDA that Teva’s ANDA Product has the same active ingredient as Evoke’s GIMOTI® Product; has the same route of administration, dosage form, and strength as Evoke’s GIMOTI® Product.

36. This action is being filed within forty-five (45) days of Evoke’s receipt of Teva’s Notice Letter.

CLAIMS FOR RELIEF

Count I—Infringement of the '281 Patent Under 35 U.S.C. § 271(e)(2)

37. Evoke incorporates each of the preceding paragraphs as if fully set forth herein.

38. Teva submitted ANDA No. 216931 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product throughout the United States before the expiration of the '281 patent. By submitting their ANDA, Teva has committed an act of infringement of one or more claims of the '281 patent under 35 U.S.C. § 271(e)(2)(A).

39. If Teva's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Teva's ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '281 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

40. On information and belief, Teva has actual and constructive knowledge of the '281 patent and is aware that submission of ANDA No. 216931 to FDA constituted an act of infringement of the '281 patent. In addition, upon information and belief, Teva has specific intent to infringe the '281 patent when it filed ANDA No. 216931. Moreover, there are no substantial non-infringing uses for Teva's ANDA Product other than as the pharmaceutical claimed in the '281 patent.

41. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product in violation of Evoke's patent rights will cause substantial and irreparable harm to Evoke for which damages are inadequate.

Count II—Infringement of the '361 Patent Under 35 U.S.C. § 271(e)(2)

42. Evoke incorporates each of the preceding paragraphs as if fully set forth herein.

43. Teva submitted ANDA No. 216931 to FDA under Section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product throughout the United States before the expiration of the '361 patent. By submitting their ANDA, Teva has committed an act of infringement of one or more claims of the '361 patent under 35 U.S.C. § 271(e)(2)(A).

44. If Teva's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Teva's ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '361 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

45. On information and belief, Teva has actual and constructive knowledge of the '361 patent and is aware that submission of ANDA No. 216931 to FDA constituted an act of infringement of the '361 patent. In addition, upon information and belief, Teva has specific intent to infringe the '361 patent when it filed ANDA No. 216931. Moreover, there are no substantial non-infringing uses for Teva's ANDA Product other than as the pharmaceutical claimed in the '361 patent.

46. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product in violation of Evoke's patent rights will cause substantial and irreparable harm to Evoke for which damages are inadequate.

PRAYER FOR RELIEF

Evoke respectfully requests the following relief:

a) A judgment that Teva has infringed the '281 and '361 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 216931 under Section 505(j) of the FDCA, and that Teva's making, using, offering to sell, or selling in the United States or importing into the United States of Teva's ANDA Product will infringe one or more claims of the '281 and '361 patents;

b) A finding that the ’281 and ’361 patents are valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 216931 shall be a date which is not earlier than the latest expiration date of the ’281 and ’361 patents, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Teva, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, sale, and/or importation into the United States, of any drug product the use of which is covered by the ’281 and ’261 patents, including Teva’s ANDA Product;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Evoke be awarded reasonable attorneys’ fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

DATED: April 7, 2022

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Evoke Pharma, Inc.

/s/ Arnold B. Calmann

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiff Evoke Pharma, Inc. hereby certifies that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: April 7, 2022

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Evoke Pharma, Inc.

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiff Evoke Pharma, Inc. hereby certifies that it seeks both monetary damages greater than $150,000 and injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: April 7, 2022

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff Evoke Pharma, Inc.

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